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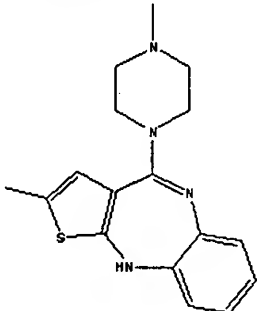


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Olanzapine [132539-06-1]

Synonyms: Olanzapine; Zyprexa; Lanzaac;

2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-b][1,5]benzodiazepine;

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Formula	C ₁₇ H ₂₀ N ₄ S	Molecular Weight	312.4318
CAS RN	132539-06-1	Melting Point (°C)	
ACX Number	X1056023-3	Boiling Point (°C)	
Density		Vapor Density	
Refractive Index		Vapor Pressure	
Evaporation Rate		Water Solubility	
Flash Point (°C)		EPA Code	
DOT Number		RTECS	
Comments			

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US Customs Pharmaceutical Appendix to the Harmonized Tariff Schedule

2133.03(e)(4) [R-1] Factors Indicative of an Experimental Purpose

**> The courts have considered a number of factors in determining whether a claimed invention was the subject of a commercial offer for sale primarily for purposes of experimentation. "These factors include: (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, ... (9) the degree of commercial exploitation during testing[,] ... (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts

made with potential customers." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353, 63 USPQ2d 1769, 1780 (Fed. Cir. 2002) quoting *EZ Dock v. Schafer Sys., Inc.*, 276 F.3d 1347, 1357, 61 USPQ2d 1289, 1296 (Fed. Cir. 2002) (Linn, J., concurring).

Once< alleged experimental activity is advanced by an applicant to explain a prima facie case under 35 U.S.C. 102(b), the examiner must determine whether the scope and length of the activity were reasonable in terms of the experimental purpose intended by the applicant and the nature of the subject matter involved. No one of, or particular combination of, factors ** is necessarily determinative of this purpose.

>See MPEP § 2133.03(e)(1) for factors indicative of commercial exploitation.<

**

* 2133.03(e) [R-1] Permitted Activity; Experimental Use

**> The question posed by the experimental use doctrine is “whether the primary purpose of the inventor at the time of the sale, as determined from an objective evaluation of the facts surrounding the transaction, was to conduct experimentation.” Allen Eng’g Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1354, 63 USPQ2d 1769, 1780 (Fed. Cir. 2002), quoting EZ Dock v. Schafer Sys., Inc., 276 F.3d 1347, 1356-57, 61 USPQ2d 1289, 1295-96 (Fed. Cir. 2002) (Linn, J., concurring). Experimentation< must be the primary purpose and any commercial exploitation must be incidental. If the use or sale was experimental, there is no bar under 35 U.S.C. 102(b). “A use or sale is experimental for purposes of section 102(b) if it represents a bona fide effort to perfect the invention or to ascertain whether it will answer its intended purpose....If any commercial exploitation does occur, it must be merely incidental to the primary purpose of the experimentation to perfect the invention.” LaBounty Mfg. v. United States Int’l Trade Comm’n, 958 F.2d 1066, 1071, 22 USPQ2d 1025, 1028 (Fed. Cir. 1992) (quoting Pennwalt Corp. v. Akzona Inc., 740 F.2d 1573, 1581, 222 USPQ 833, 838 (Fed. Cir. 1984)). “The experimental use exception...does not include market testing where the inventor is attempting to gauge consumer demand for his claimed invention. The purpose of such activities is commercial exploitation and not experimentation.” In re Smith, 714 F.2d 1127, 1134, 218 USPQ 976, 983 (Fed. Cir. 1983)